REASONED OPINION

Setting of new MRLs for BAS 650 F in table and wine grapes, potatoes, tomatoes, peppers, cucumbers, courgettes, melons and lettuce [1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

This reasoned opinion, published on 9 November 2009, replaces the earlier version published on 3 November 2009[3].

SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, the Netherlands, hereafter referred to as the Evaluating Member State (EMS), received an application from BASF Germany to set new MRLs for BAS 650 F for certain crops for which authorisations will be requested. In order to accommodate for intended uses in Northern and Southern EU Member States, it is proposed to set MRLs for table and wine grapes at 10 mg/kg, in potatoes at 0.01 mg/kg, in tomatoes at 2 mg/kg, in peppers at 2 mg/kg, in cucurbits (edible peel) at 0.5 g/kg, in cucurbits (inedible peel) at 1 mg/kg, in lettuce at 20 mg/kg and in lamb's lettuce at 50 mg/kg. The Netherlands drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 8 July 2009. It is noted that BAS 650 F is a new active substance for which the peer review process under Directive 91/414/EEC is not yet finalised.

Based on the evaluation report and the Draft Assessment Report (DAR) prepared by the Netherlands as the designated Rapporteur Member State (RMS) under Directive 91/414/EEC, EFSA derived the following conclusions regarding this application.

The toxicological profile of BAS 650 F was assessed by the RMS in the framework of the evaluation according to Directive 91/414/EEC. The data were sufficient to conclude on an ADI value of 10 mg/kg. The RMS concluded that no ARfD has to be established because no acute effects have been observed.

The metabolism of BAS 650 F in primary and rotational crops was investigated. Based on the results of these studies a residue definition for plant commodities was proposed as parent compound which is applicable for monitoring and risk assessment.

The supervised field trials submitted in support of the intended uses in grapes, potatoes, tomatoes, peppers, cucumber, courgettes, melons, head lettuce and lamb's lettuce were sufficient to derive MRL proposals for these crops.

1 On request from the European Commission, Question No EFSA-Q-2009-00700, issued on 30 October 2009.
2 Correspondence: praper.mrl@efsa.europa.eu
3 In the table regarding the processing factors on page 3, 14f and 20 the entries in the columns "Median PF" and "Comments" were corrected for wine grapes (red wine, rosé wine, and raisins).

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BAS 650 F was demonstrated to be stable under conditions simulating pasteurisation, baking/brewing/boiling and sterilisation. Processing studies are available for grapes and tomatoes which allow predicting residue concentrations in processed products derived from grapes and tomatoes.

The occurrence of BAS 650 F residues in rotational crops was also investigated. The only residues observed in significant concentrations were the soil metabolites M650F03 and M650F04 which were considered as toxicologically not relevant.

The use of the active substance on potatoes, the only crop that can be used as feed item, does not lead to measurable residues. Thus, no significant residues of BAS 650 F or related metabolites are expected in food of animal origin.

The consumer intake calculation was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model), using the STMR values as derived from the supervised field trials for predicting the expected long-term exposure. The estimated maximum daily intakes for the diets included in the EFSA PRIMo were in all cases insignificant (below 0.1 % of the ADI). Therefore it is concluded that the long-term intake of residues of BAS 650 F resulting from the uses that have been considered by EFSA in the framework of this assessment is unlikely to present a public health concern. Since no ARfD is necessary, an acute consumer health risk is not expected.

In conclusion, the following temporary MRLs are proposed for the intended uses assessed in this reasoned opinion which are recommended to be included in Annex III of Regulation 396/2005:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
BAS 650 F			
Table grapes	Currently the default MRL of 0.01 mg/ kg is applicable (Art. 18 (1) (b))	5	The proposed MRLs are sufficiently supported by data. The dietary risk assessment did not reveal a potential consumer health concern.
Wine grapes		5	
Potatoes		0.01(*)	
Tomatoes		2	
Peppers		2	
Cucumber		0.5	
Courgette		0.5	
Melons		1	
Water melon		1	
Pumpkin		1	
Lettuce		20	
Lamb's lettuce		50	

(*): Indicates that the MRL is set at the limit of analytical quantification.

From processing studies on grapes and tomatoes the following processing factors were derived which are recommended to be included in Annex VI of Regulation 396/2005:

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
BAS 650 F				
Wine grapes, red wine	4	0.023	1	0.012 – 0.032
Wine grapes, rosé wine	4	0.004	1	<0.01 – 0.055
Wine grapes, raisins	4	3.4	1	1.9 – 6.23
Tomatoes, canned tomatoes	4	0.019	1	0.012 – 0.032
Tomatoes, peeled tomatoes	4	0.025	1	0.01– 0.04

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

As the DAR has not yet been peer reviewed, the conclusions reached in this reasoned opinion have to be considered as provisional and might be reconsidered once the peer review under Directive 91/414/EEC has been finalised.

KEY WORDS

BAS 650 F, ametoctradin, table- and wine grapes, potatoes, tomatoes, peppers, cucumber, courgette, melons, lettuce (head lettuce, lamb's lettuce), MRL application, Regulation (EC) No 396/2005, consumer risk assessment

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

The Netherlands, hereafter referred to as the evaluating Member State (EMS), received an application from the company BASF[4] to set new MRLs for the active substance BAS 650 F in table and wine grapes, potatoes, tomatoes, peppers, curcurbits (edible and inedible peel) lettuce and lamb's lettuce. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 8 July 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00700 and the following subject:

BAS 650 F - Application to set new MRLs for BAS 650 F in wine and table grapes at 10 mg/kg, in potatoes at 0.01 mg/kg, in tomatoes at 2 mg/kg, in peppers at 2 mg/kg, in cucurbits (edible peel) at 0.5 mg/kg, in cucurbits (inedible peel) at 1 mg/kg, in lettuce at 20 mg/kg and in lamb's lettuce at 50 mg/kg.

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

TERMS OF REFERENCE

According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 8 October 2009.

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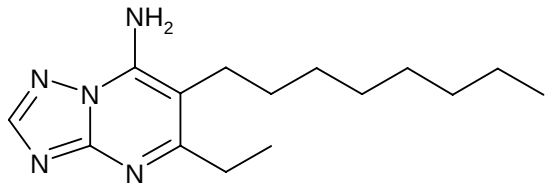
THE ACTIVE SUBSTANCE AND ITS USE PATTERN

BAS 650 F is the ISO development code for 5-ethyl-6-octyl[1,2,4]triazolo[1,5-a]pyrimidin-7-amine. The provisional ISO common name for the substance is ametoctradin.



Molecular mass: 275.4

BAS 650 F is a new active substance which acts on *Peronosporomycetes (oomycete*) fungi. The compound has preventive properties; it inhibits zoospore development and zoospore and zoosporangium infection of host plants.

BAS 650 F will be evaluated in the framework of Directive 91/414/EEC as a new active substance, the Netherlands acting as the designated Rapporteur Member State (RMS). The representative uses supported by the manufacturer in the peer review are the foliar application on tomatoes and potatoes. The peer review of the active substance is currently in an early stage and a final decision concerning the inclusion in Annex I of Directive 91/414/EEC is not expected within the next months. The Draft Assessment Report has been submitted to EFSA in September 2009.

Currently, no specific MRLs are established in Regulation (EC) No 396/2005. Therefore the default MRL of 0.01 mg/kg is applicable for all crops. No CXLs are established by Codex Alimentarius.

The applicant BASF intends to request the provisional authorisations for a number of crops in Northern and Southern Member States for which now the MRL request has been prepared by the RMS. SC and WG-formulations have been developed which contain as a second active substance dimethomorph or metiram. The intended GAPs for potatoes, tomatoes (field and glasshouse use), grapes, pepper (glasshouse), cucumber, courgette, melons, water melons, pumpkins, lettuce (head lettuce and lamb's lettuce) are presented in Appendix A.

It is noted that the RMS did not provide the information whether the provisional authorisations have already been requested in the Member States concerned.

EFSA bases its risk assessment on the evaluation report submitted by the RMS (The Netherlands, 2009a) and the Draft Assessment Report prepared under Directive 91/414/EEC (The Netherlands, 2009b).

Since the peer review under Directive 91/414/EEC has not yet been finalised, the conclusions reached in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the conclusions of the peer review.

ASSESSMENT

1. Methods of analysis

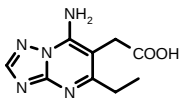
1.1. Methods for enforcement of residues in food of plant origin

Analytical methods for the determination of BAS 650 F and the metabolites M650F03[5] and M650F04[6] have been developed. The method is based on extraction with methanol/water, clean up and final determination with HPLC/MS/MS. The LOQ achievable in wheat grain, tomato, lettuce, potato, onion, sunflower, grapes and oranges was 0.01 mg/kg for each component. An independent laboratory validation was performed which demonstrated that the method is suitable for post-registration purposes for dry crops, commodities with high water content, commodities with high fat content and fruits with a high acid content (The Netherlands, 2009b). No information is provided whether BAS 650 F residues can be measured by multi-methods.

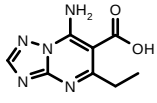
1.2. Methods for enforcement of residues in food of animal origin

A validated HPLC method with MS/MS detection is available to analyse milk, cream, eggs and animal tissues regarding residues of BAS 650F. The LOQ for which satisfactory results were achieved is 0.01 mg/kg (The Netherlands, 2009b).

[5] M650F03: (7-amino-5-ethyl [1,2,4]triazolo [1,5-a]pyrimidin-6-yl) acetic acid



[6] M650F04: 7-amino-5-ethyl [1,2,4]triazolo [1,5-a]pyrimidine-6-carboxylic acid



2. Mammalian toxicology

The toxicological properties of BAS 650 F were assessed by the RMS in the framework of the DAR (The Netherlands, 2009b). The studies presented by the applicant were sufficient to derive an ADI proposal. Due to the low acute toxicity the RMS concluded that it is not necessary to set an ARfD. The proposed ADI is reported in Table 2-1.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
BAS 650F					
ADI	NL	2009	10	2 yr rat	100
ARfD	NL	2009		Not necessary	

Several toxicological studies with metabolites M650F03 and M650F04 were available (Ames test, *in vitro* gene mutation test, chromosome aberration test in mammalian cells, *in vivo* micronucleus test (for M650F03 only)). The RMS concluded that these metabolites are of no toxicological relevance (The Netherlands, 2009b).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The nature of residues resulting from a foliar application of BAS 650 F was investigated in several crops (The Netherlands, 2009b):

- Lettuce (leafy vegetables): foliar application of 3*0.0223 kg a.s./ha (7 to 10 d interval)
- Potatoes (root and tuber vegetables): foliar application of 3*0.4408 kg a.s./ha (14 d interval)
- Tomatoes (fruits and fruiting vegetables): foliar application of 3*0.3 kg a.s./ha (7 d interval).

The dosing regimes in the metabolism studies are comparable with the intended uses regarding the timing of the application, the growth stage and the waiting period.

In lettuce the major compound found seven days after the last application was parent BAS 650 F which accounted for 98.9 % TRR (8.39 mg/kg). No metabolites were identified.

In potatoes, the majority of the residues found in immature and mature leaves (22 and 45 mg eq/kg) consisted of parent compound (95 and 85% of the TRR, respectively); none of the metabolites accounted for more than 2% of the TRR. In the immature and mature tuber 0.025 and 0.041 mg eq/kg were detected. In immature tuber the major compounds identified were the parent BAS 650 F (67% of TRR) and metabolite M650F03 (13% of TRR, 0.033 mg /kg). In mature tuber the residues consisted mainly of metabolite M650F03 (40% of TRR) and M650F04 (27% of TRR) whereas the parent compound was a minor compound accounting for 3.6% of TRR only. Since M650F03 and M650M04 were also identified as soil metabolites and these compounds were found only in tubers and not in directly treated leaves, it is assumed that they are taken up from the soil.

In tomatoes the residues in the fruit one day after the last treatment consisted of parent BAS 650 F which accounted for 99.1% of the TRR (0.357 mg/kg). No metabolites were identified. In leaves the results are comparable with the results obtained on potato leaves (9.2 mg eq/kg, parent compound accounted for 98.6% of the TRR). Also on tomato leaves, no metabolites were identified.

In conclusion, in leaves and fruit directly treated with BAS 650 F, the main residue found was the parent compound. No metabolites were found in the plant tissues investigated, except in mature potato tuber. Since the metabolites M650F03 and M650F04 were also identified as soil metabolites, it is assumed that they were formed in soil and taken up directly from soil. From the toxicological studies it was concluded that these metabolites are toxicologically not relevant. Thus, the residue definition proposed by the RMS for monitoring and risk assessment comprises the parent compound BAS 650 F only. Since metabolism was comparable in three crops representing different crop groups, the proposed residue definition should be applicable as a general residue definition for all crops.

3.1.1.2. Magnitude of residues

Potatoes: In total 8 supervised field trials covering one growing season performed in Northern Europe (4 trials) and Southern Europe (4 trials) were submitted. All trials were performed according to the critical GAP for NEU and SEU with the SC formulation which contained also dimethomorph. Seven days after the last application, no BAS 650 F residues were detectable in potato tuber. It is also noted

that none of the metabolites observed in the metabolism study in potatoes (M650F03 and M650M04) was detected. EFSA concludes that 4 trials for NEU and SEU each are sufficient to demonstrate the no-residue situation and to derive a MRL proposal.

Tomatoes: For tomatoes the manufacturer intends to apply for authorisations for outdoor and indoor use in NEU (SC formulation) and for an indoor use in NEU and SEU (WG formulation). For the SC formulation a PHI of 1 day is envisaged whereas for the WG formulation the last application is planned 3 days before harvest. The supervised field trials provided demonstrated that the critical use for deriving an MRL is the indoor use in NEU with 1 d PHI. Sufficient trials are available to derive a MRL proposal.

Grapes: 8 supervised field trials (4 NEU and 4 SEU) each covering two growing seasons are available. The trials were performed in accordance with the intended GAP. In some trials higher residues were observed at a longer PHI than at the defined minimum PHI. In these cases this data point was selected to derive the MRL proposal. In total, the data are sufficient to derive a MRL proposal for table and wine grapes.

Pepper: In total 8 indoor trials performed in NEU (4 trials) and SEU (4 trials) covering one growing season are available. The data are considered sufficient to derive a MRL proposal for the intended indoor use on peppers.

Cucumber, courgette: In total 2 outdoor residue trials on cucumber performed in NEU were submitted. The database is not sufficient to derive a MRL proposal for the outdoor use in Northern Europe. For SEU in total 8 trials (5 trials on courgette and 3 trials on cucumber) corresponding with the intended GAP (outdoor use) were submitted. The trials which were performed over two growing seasons are sufficient to derive a MRL proposal. In addition, for the indoor use, in total 8 trials (4 NEU and 4 SEU) on courgette and cucumber are available; a MRL proposal was derived for the intended GAP.

Melons: 4 outdoor trials on melons performed in NEU and 8 outdoor trials from SEU are available. The data are sufficient to derive a MRL proposal.

Lettuce: In support of the NEU and SEU outdoor use on lettuce, 8 trials for each region have been provided. In both zones trials were performed on head forming and open leaf varieties. For the indoor use, in total 8 trials are available, again on head forming and open leaf varieties. The data are sufficient to derive a MRL proposal.

Lamb's lettuce: In total 8 trials on lamb's lettuce (4 NEU and 4 SEU) are available to support the outdoor use. Since lamb's lettuce is a minor crop, the data are sufficient for deriving a MRL proposal. The 4 indoor trials (2 NEU and 2 SEU) demonstrated that the indoor use is the most critical use regarding the expected residues. Data are sufficient to derive a MRL proposal for lamb's lettuce.

In table 3-1 the results of the supervised field trials, the related risk assessment input values (HR, STMR) and the MRL proposals are summarised.

BAS 650 F residues in grapes, potatoes, tomatoes, peppers, cucumber, melons and lettuce were determined using a validated method which allows the quantification of parent compound and M650F03 and M650F04 in concentrations at or above 0.01 mg/kg. BAS 650 F residues were demonstrated to be stable during frozen storage for at least 16 months in potatoes and grapes. On tomatoes and lettuce storage stability was proven for 3 and 2 years, respectively. The analyses of all samples taken in the supervised field trials were performed within the period of 16 months. Thus, the results derived in supervised field trials are valid regarding storage stability and the analytical method applied.

Table 3-1. Overview of the available residues trials data

Commodity	Region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement BAS 650 F	Risk assessment BAS 650 F					
Potatoes	NEU	Outdoor	4*<0.01	4*<0.01	0.01	0.01	**0.01**	1	
Potatoes	SEU	Outdoor	4*<0.01	4*<0.01	0.01	0.01	0.01	1	
Tomatoes	NEU	Outdoor	0.089; 0.11; 0.14; 0.16[(e)]; 0.24[(e)]; 0.32[(e)]; 0.36; 0.37;	0.089; 0.11; 0.14; 0.16[(e)]; 0.24[(e)]; 0.32[(e)]; 0.36; 0.37;	0.2	0.37	1	1	In support of GAP fro the SC formulation, 1 d PHI Rber=0.66 Rmax=0.59
Tomatoes	SEU	Outdoor	0.04; 0.062[(e)]; 0.12; 0.15; 0.16; 0.19[(e)]; 0.26; 0.45	0.04; 0.062[(e)]; 0.12; 0.15; 0.16; 0.19[(e)]; 0.26; 0.45	0.155	0.45	1	1	No outdoor use intended at the moment, but supervised field trials were presented in the ER and the DAR. Data represent 1 d PHI. Rber=0.42 Rmax=0.60
Tomatoes	NEU	Indoor	0.13; 0.17; 0.17[(e)]; 0.25; 0.26; 0.39; 0.71; 1.06;	0.13; 0.17; 0.17[(e)]; 0.25; 0.26; 0.39; 0.71; 1.06;	0.26	1.06	**2**	1	In support of GAP for SC formulation with 1 d PHI Rber=0.94 Rmax=1.44
Tomatoes	NEU+ SEU	Indoor	0.024; 0.09; 0.10; 0.11; 0.11; 0.13; 0.13; 0.13; 0.14; 0.15; 0.17; 0.25; 0.26; 0.39; 0.48; 1.05;	0.024; 0.09; 0.10; 0.11; 0.11; 0.13; 0.13; 0.13; 0.14; 0.15; 0.17; 0.25; 0.26; 0.39; 0.48; 1.05;	0.13	1.05	1	1	In support of GAP for WG formulation with 3 d PHI Rber=0.505 Rmax=0.86

Commodity	Region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [b]	HR (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement BAS 650 F	Risk assessment BAS 650 F					
Wine grapes → table and wine grapes	NEU	Outdoor	0.17; 0.46; 0.60; 0.84; 1.08; 1.7; 2.2; 4.2	0.17; 0.46; 0.60; 0.84; 1.08; 1.7; 2.2; 4.2	0.96	4.2	**5**	1	Rber=3.65 Rmax=5.58
Wine grapes → table and wine grapes	SEU	Outdoor	0.15; 0.22; 0.37; 0.72[e]; 1.1[e]; 1.12; 2.72[e]; 3.1[e]	0.15; 0.22; 0.37; 0.72[e]; 1.1[e]; 1.12; 2.72[e]; 3.1[e]	0.91	3.1	**5**	1	Rber=3.04 Rmax=4.79
Pepper	NEU + SEU	Indoor	0.20[e]; 0.21; 0.28; 0.34[e]; 0.37[e]; 0.47; 0.79; 0.90[e]	0.20[e]; 0.21; 0.28; 0.34[e]; 0.37[e]; 0.47; 0.79; 0.90[e]	0.36	0.9	**2**	1	Rber=1.1 Rmax=1.29
Cucumber	NEU	Outdoor	0.37; 0.38	0.37; 0.38				1	Not sufficient trials to derive MRL proposal
Cucumber, courgette	SEU	Outdoor	0.031[f]; 0.038[e]; 0.05[f]; 0.064[f]; 0.07[f]; 0.09; 0.11; 0.17	0.031[f]; 0.038[e]; 0.05[f]; 0.064[f]; 0.07[f]; 0.09; 0.11; 0.17	0.067	0.17	0.3	1	Rber=0.19 Rmax=0.22
Cucumber, courgette	NEU + SEU	Indoor	0.033[f]; 0.037[e]; 0.082[f]; 0.089[f]; 0.14[e],[f]; 0.15; 0.18; 0.24	0.033[f]; 0.037[e]; 0.082[f]; 0.089[f]; 0.14[e],[f]; 0.15; 0.18; 0.24	0.015	0.24	**0.5**	1	Rber=0.32 Rber=0.35
Melon → watermelons, pumpkins	NEU	Outdoor	0.05[e]; 0.12[e]; 0.19[e]; 0.19	0.05[e]; 0.12[e]; 0.19[e]; 0.19	0.155	0.19	0.5	1	Rber=0.38 Rmax=0.48
Melon → watermelons, pumpkins	SEU	Outdoor	0.08; 0.08; 0.13; 0.13; 0.13[e]; 0.22[e]; 0.33[e]; 0.38[e]	0.08; 0.08; 0.13; 0.13; 0.13[e]; 0.22[e]; 0.33[e]; 0.38[e]	0.13	0.38	**1**	1	Rber=0.50 Rmax=0.55
Lettuce, head	NEU	Outdoor	0.32; 0.43; 0.89; 1.31; 1.8[g]; 1.8; 2.02; 2.08	0.32; 0.43; 0.89; 1.31; 1.8[g]; 1.8; 2.02; 2.08	1.56	2.08	5	1	Rber=3.71 Rmax=3.59
Lettuce, head	SEU	Outdoor	0.069; 0.64; 0.65; 1.17; 1.33; 1.67; 2.2[g]; 3.9[g]	0.069; 0.64; 0.65; 1.17; 1.33; 1.67; 2.2[g]; 3.9[g]	1.25	3.9	5	1	Rber=3.6 Rmax=5.25

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement BAS 650 F	Risk assessment BAS 650 F					
Lettuce, head	NEU + SEU	Indoor	0.03(e); 1.2(g); 1.2; 1.7; 6.3(g); 7.5(e)(g); 9.2(e)(g); 10	0.03(e); 1.2(g); 1.2; 1.7; 6.3(g); 7.5(e)(g); 9.2(e)(g); 10	4.0	10	**20**	1	Rber=15.9 Rmax=17.5
Lamb's lettuce	NEU	Outdoor	2.4; 6.29; 8.1; 11.3	2.4; 6.29; 8.1; 11.3	7.2	11.3	20	1	Rber=17.8 Rmax=26.1
Lamb's lettuce	SEU	Outdoor	4.7; 10; 14.3; 20	4.7; 10; 14.3; 20	12.15	20	40	1	Rber=31.5 Rmax=45.6
Lamb's lettuce	NEU + SEU	Indoor	15; 16; 24; 33	15; 16; 24; 33	20	33	**50**	1	Rber=52.5 Rmax=65

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(e): The higher residue value measured at longer PHI than PHI indicated in GAP was selected to derive MRL.
(f): Trial was performed on courgette.
(g): Trial on open leaf lettuce variety
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

A hydrolysis study simulating conditions of pasteurisation baking/brewing/boiling and sterilisation was evaluated in the DAR (The Netherlands, 2009b). Under the conditions tested, BAS 650 F was the only component identified; no degradation products were detected. From this study it is concluded that BAS 650 F is hydrolytically stable at elevated temperatures (90 to 120°C) at a pH between 4 and 7.

The Netherlands note in the Evaluation Report that the nature of residues derived in fermentation processes has not been investigated. Although currently not required in the EU guidance documents (European Commission, 1997), EFSA agrees with the EMS that such a study on the nature of residues in wine would be desirable. However, for the time being, lacking more specific data on fermentation, the same residue definition as for unprocessed plant products (parent BAS 650 F only) would be applicable for wine as for all other processed commodities.

Regarding the magnitude of residues in wine and other commodities on the basis of grapes, specific processing studies were submitted by the applicant in the framework of the MRL application (The Netherlands, 2009a). Four processing studies were performed with grapes treated with BAS 650 F (four foliar spray applications with 1080 g a.s./ha (3-4N)). The grapes were processed to rosé wine, red wine and raisins. Must, wet pomace (red wine and rosé wine), must deposit, must separated, pasteurize juice, yeast deposit, rosé wine, red wine, raisins and stalks were analysed for residues of parent compound and the metabolites M6520F03 and M650M04. Metabolites were not detectable in any of the samples analysed. The median processing factors for commodities intended for human consumption are summarised in table 3-2.

Specific processing studies are also available for potatoes and tomatoes. These studies are presented in the DAR (The Netherlands, 2009b). The processing factors derived for the processed commodities most relevant for consumption and enforcement are presented in table 3-2. The studies also demonstrated that by washing the residues could be reduced to 13 % compared with the unwashed tomatoes.

In the processing study for potatoes no residues were observed in the unprocessed tuber although they were treated with an exaggerated dose rate compared with the intended GAP (3N). In none of the processed products (chips, flakes, microwave boiled potatoes, peel, peeled potato, fried potato and cooked potato) measurable residues of BAS 650 F were detectable (all results <0.01 mg/kg). Since no residues were present in the raw unprocessed and the processed commodities investigated, no processing factors have to be derived.

The EMS also reported the results of a processing study for gherkins. However, since the current application does not cover the use on gherkins, the information is considered as not relevant in the framework of this application.

Table 3-2. Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
BAS 650 F				
Wine grapes, red wine	4	0.023	1	0.012 – 0.032
Wine grapes, rosé wine	4	0.004	1	<0.01 – 0.055
Wine grapes, raisins	4	3.4	1	1.9 – 6.23
Tomatoes, canned tomatoes	4	0.019	1	0.012 – 0.032
Tomatoes, peeled tomatoes	4	0.025	1	0.02– 0.04

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Tomatoes, juice (raw juice)	4	0.235	1	0.14 – 0.7

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

The median processing factors reported in Table 3-2 are recommended to be included in Annex VI of Regulation (EC) No 396/2005.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Since the use of BAS 650F is intended in crops which are relevant for crop rotation, the possible occurrence of residues of parent compound or soil metabolites have to be considered. The major soil metabolites expected after aerobic degradation are M650F01[7], M650F03 and M650F04. In all soil types tested the DT_{90} values (aerobic conditions, laboratory studies) for parent compound, M650F01 and M650F02 were all below 71 days. For the metabolites M650F03 and M650F04 the reported DT_{90} values exceeded the trigger value of 100 days in the laboratory studies and in the field studies. Thus, these metabolites have to be considered in rotational crops.

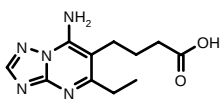
3.1.2.2. Nature of residues

A confined rotational crop study is reported in the DAR (The Netherlands, 2009b) where 1.44 kg a.s./ha of the radiolabelled parent compound was applied to bare soil (1.5 N compared with the critical GAPs). Spring wheat, lettuce and white radish were planted 30, 120 and 365 d after the treatment. BAS 650 F residues were below the LOQ in all samples except in ripe lettuce leaves (0.009 mg/kg, 30 d plant back interval) and wheat forage and straw (0.005 mg/kg and 0.044 mg/kg, respectively, all 30 d plant back interval). Residues of the soil metabolites M650F03 and M650F04 were found in wheat, carrots, cauliflower and lettuce in varying levels. Besides the soil metabolites M650F03 and M650F04 which are the major metabolites identified in rotational crops, other minor metabolites were identified in radishes, lettuce and cereal grain which did not exceed 0.01 mg/kg or 10% of the TRR. In forage, straw and chaff from spring wheat new metabolites not observed in soil were detected in significant concentrations (>0.01 mg/kg), but none of them exceeded 10% of the TRR. These additional metabolites identified are structurally closely related to the soil metabolites.

From the rotational crops studies it is concluded that the major residues expected will be the soil metabolites M650F03 and M650F04 which are toxicological not relevant (see section 2).

EFSA is of the opinion that for rotational crops no specific residue definition is required because the expected residues are not of toxicological significance.

[7] M650F01, 4-(7-amino-5-ethyl [1,2,4]triazolo, [1,5-a]pyrimidin-6-yl) butanoic acid,



3.1.2.3. Magnitude of residues

No significant concentrations of toxicologically relevant residues are expected in rotational crops. It is not necessary to specify risk mitigation measures.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Among the crops assessed in the framework of this application, only potatoes are used as a feed item for livestock. The other crops (tomatoes, grapes, pepper, cucumber, courgette, melons, head lettuce and lamb's lettuce) are therefore not relevant regarding the potential occurrence of residues in products of animal origin. Since no detectable residues were observed in potatoes, a theoretical estimation of dietary intake is calculated with the LOQ of 0.01 mg/kg.

Table 3-3. Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
BAS 650 F				
Potatoes	0.01	STMR (=LOQ)	0.01	HR (=LOQ)

The results of the theoretical dietary burden calculation are reported in the following table.

Table 3-4. Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded ?
BAS 650 F					
Dairy ruminants	0.000727	0.000727	Potatoes	0.020000	No
Meat ruminants	0.001714	0.001714	Potatoes	0.039943	No
Poultry	0.000842	0.000842	Potatoes	0.013305	No
Pigs	0.001600	0.001600	Potatoes	0.040000	No

In none of the cases calculated the trigger value for the dietary intake (0.1 mg/kg feed, dry matter) is exceeded. Thus the setting of MRLs for animal products is not necessary. In the next section a brief summary of the metabolism studies in livestock is given with the view of deriving a residue definition for animal products.

3.2.2. Nature of residues

A metabolism study in poultry is reported in the DAR (The Netherlands, 2009b). Laying hens received feed for 10 consecutive days containing radiolabelled BAS 650 F in concentration of 11.5 mg/kg dry feed, equivalent to 0.81 mg/kg bw/d. The dose rate is the 1000 fold theoretical dietary burden

calculated as reported in table 3-4. The highest radioactivity concentrations in edible tissues were found in liver (0.11 mg eq/kg) followed by muscle (0.026 mg eq/kg) and fat (0.014 mg eq/kg). In eggs the TRR reached a plateau of 0.04 mg eq/kg within 7 days. Compounds identified in the edible tissues and eggs were parent compound (in eggs and fat only), M650F01 and M650F06[8]. In none of the matrices analysed the identified residues exceeded a concentration of 0.0002 mg/kg.

The metabolism in lactating ruminants was investigated in a study with goats which received daily oral doses of 12 mg/kg feed, equivalent to 0.49 – 0.51 mg/kg bw/d. The dose level corresponds 300 times the calculated theoretical dietary burden for ruminants. The highest radioactivity concentrations in edible products were found in liver (0.1 mg eq/kg), followed by milk (0.097 mg eq/kg), kidney (0.036 mg eq/kg), fat (0.016 mg eq/kg) and muscle (0.01 mg eq/kg). Parent BAS 650 F was not identified in any of the edible tissues or milk. The only components identified were M650F01 (milk, liver, kidney and fat), M65F06 (milk, liver, kidney and fat) and M650F09[9] (milk, kidney fat). In all matrices the identified residues did not exceed a concentration of 0.014 mg/kg.

The Netherlands proposed in the DAR not to establish a residue definition since the expected dietary burden resulting form the use of BAS 650F on feed is negligible. Since the relevant metabolism studies are available, EFSA proposes to define the relevant residue for animal commodities as parent compound, both for monitoring and risk assessment. However, no residues are expected at the dietary intake resulting from the intended uses under consideration.

3.2.3. Magnitude of residues

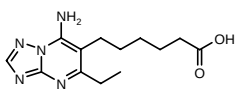
Because of the insignificant dietary intake no feeding studies are necessary.

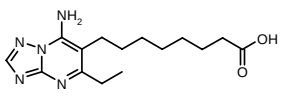
4. Consumer risk assessment

The consumer intake calculation was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model), using the STMR values as derived from the supervised field trials (see table 4-1).

Table 4-1. Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
BAS 650 F				
Potatoes	0.01	STMR (=LOQ)	Not relevant since no ARfD was allocated for the active substance	
Tomatoes	0.26	STMR (NEU, indoor)		
Table grapes	0.96	STMR (NEU)		

[8] M650F06: 6-(7-amino-5-ethyl [1,2,4]triazolo [1,5-a]pyrimidin-6-yl) hexanoic acid, 

[9] M650F09: 8-(7-amino-5-ethyl [1,2,4]triazolo [1,5-a]pyrimidin-6-yl) octanoic acid, 

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Wine grapes	0.96	STMR (NEU)		
Peppers	0.36	STMR		
Cucumber Courgette	0.067	STMR (SEU, outdoor)		
Melon Watermelons Pumpkins	0.155	STMR (NEU)		
Lettuce, head	4.0	STMR (indoor)		
Lamb's lettuce	20	STMR (indoor)		

The estimated maximum daily intakes for the diets included in the EFSA PRIMo were in all cases insignificant (below 0.1 % of the ADI). Therefore it is concluded that the long-term intake of residues of BAS 650 F resulting from the uses that have been considered by EFSA in the framework of this assessment is unlikely to present a public health concern. The detailed calculations are presented in the Appendix B.

Since no ARfD is necessary, an acute consumer health risk is not expected.

It is noted that the consumer risk assessment may need to be revised in the light of the decisions that will be taken in the peer review under Directive 91/414/EEC.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of BAS 650 F was assessed by the RMS in the framework of the evaluation according to Directive 91/414/EEC. The data were sufficient to conclude on an ADI value of 10 mg/kg. The RMS concluded that no ARfD has to be established because no acute effects have been observed.

The metabolism of BAS 650 F in primary and rotational crops was investigated. Based on the results of these studies a residue definition for plant commodities was proposed as parent compound which is applicable for monitoring and risk assessment.

The supervised field trials submitted in support of the intended uses in grapes, potatoes, tomatoes, peppers, cucumber, courgettes, melons, head lettuce and lamb's lettuce were sufficient to derive MRL proposals for these crops.

BAS 650 F was demonstrated to be stable under conditions simulating pasteurisation, baking/brewing/boiling and sterilisation. Processing studies are available for grapes and tomatoes which allow predicting residue concentrations in processed products derived from grapes and tomatoes.

The occurrence of BAS 650 F residues in rotational crops was also investigated. The only residues observed in significant concentrations were the soil metabolites M650F03 and M650F04 which were considered as toxicologically not relevant.

The use of the active substance on potatoes, the only crop that can be used as feed item, does not lead to measurable residues. Thus, no significant residues of BAS 650 F or related metabolites are expected in food of animal origin.

The consumer intake calculation was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model), using the STMR values as derived from the supervised field trials for predicting the expected long-term exposure. The estimated maximum daily intakes for the diets included in the EFSA PRIMo were in all cases insignificant (below 0.1 % of the ADI). Therefore it is concluded that the long-term intake of residues of BAS 650 F resulting from the uses that have been considered by EFSA in the framework of this assessment is unlikely to present a public health concern. Since no ARfD is necessary, an acute consumer health risk is not expected.

RECOMMENDATIONS

The following temporary MRLs are proposed for the intended uses assessed in this reasoned opinion which are recommended to be included in Annex III of Regulation 396/2005:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
BAS 650 F			
Table grapes	Currently the default MRL of 0.01 mg/ kg is	5	The proposed MRLs are sufficiently supported by data. The dietary risk assessment did not reveal a potential consumer health concern.
Wine grapes		5	
Potatoes		0.01(*)	

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Tomatoes	applicable (Art. 18 (1) (b))	2	
Peppers		2	
Cucumber		0.5	
Courgette		0.5	
Melons		1	
Water melon		1	
Pumpkin		1	
Lettuce		20	
Lamb's lettuce		50	

(*): Indicates that the MRL is set at the limit of analytical quantification.

From processing studies on grapes and tomatoes the following processing factors were derived which are recommended to be included in Annex VI of Regulation 396/2005:

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
BAS 650 F				
Wine grapes, red wine	4	0.023	1	0.012 – 0.032
Wine grapes, rosé wine	4	0.004	1	<0.01 – 0.055
Wine grapes, raisins	4	3.4	1	1.9 – 6.23
Tomatoes, canned tomatoes	4	0.019	1	0.012 – 0.032
Tomatoes, peeled tomatoes	4	0.025	1	0.03– 0.04

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

As the DAR has not yet been peer reviewed, the conclusions reached in this reasoned opinion have to be considered as provisional and might be reconsidered once the peer review under Directive 91/414/EEC has been finalised.

REFERENCES

The Netherlands, 2009a. Evaluation report on the setting of MRLs for BAS 650 F in grape, potatoes, tomato, pepper, cucurbits edible peel, cucurbits inedible peel and lettuce prepared by the evaluating Member State Netherlands (Ctgb) under Article 8 of Regulation (EC) No 396/2005, 7 April 2009.

The Netherlands, 2009b. Draft Assessment Report (DAR) on the active substance BAS 650 F prepared by the rapporteur Member State Netherlands in the framework of Directive 91/414/EEC, September 2009.

European Commission, 1997. Appendix E – Processing Studies. 7035/VI/95 rev.5, 22 July 1997.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Identification of GAP of intended uses in Northern and Southern Europe

Crop and/or situation	Member State or Country	F, G or I	Pests or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
				type	conc of as	method kind	growth stage	number (range)	interval (days)	as (kg/hl)	water (l/ha)	as (kg/ha)		
Potatoes	NEU	F	*Phytophthora infestans*	SC	300 g/l[(1)] + 225 g/l[(2)]	Foliar spraying	BBCH 15 - 89	3-4	5 - 10	0.048-0.24 0.024-0.24	100-500 100-1000	0.24	7	Authorisation intended for AT, BE, BG, DE, EE, ES, FR, GR, HU, IE, IT, LT; LV, NL, PL, PT, RO, UK
Potatoes	SEU	F	*Phytophthora infestans*	SC	300 g/l[(1)] + 225 g/l[(2)]	Foliar spraying	BBCH 15 - 89	3-4	5 - 10	0.048-0.24 0.024-0.24	100-500 100-1000	0.24	7	
Tomatoes	NEU	F	*Phytophthora infestans*	SC	300 g/l[(1)] + 225 g/l[(2)]	Foliar spraying	BBCH 10 – 89	3	7-10	0.024 -0.12	200 - 1000	0.24	1	Intended use for Annex I inclusion; ; Authorisation intended for UK, DE, NL
Tomatoes	NEU	G	*Phytophthora infestans*	SC	300 g/l[(1)] + 225 g/l[(2)]	Foliar spraying	BBCH 10 – 89	3	7-10	0.024 -0.12	200 - 1000	0.24	1	Intended use for Annex I inclusion; ; Authorisation intended for UK , DE, NL
Tomatoes	NEU + SEU	G	*Phytophthora infestans*	WG	120 g/l[(1)] + 440 g/l[(3)]	Foliar spraying	BBCH 10 - 89	3	7 - 10	-	-	0.24[(1)] + 0.88[(3)]	3	Alternative GAP/formulation Authorisation intended for ES, IT, PT and NEU (MS not specified)
Grapes (table and wine grapes)	NEU	F	*Plasmopara viticola*	WG	120 g/l[(1)] + 440 g/l[(3)]	Foliar spraying	BBCH 19 - 83	3	10 - 12	-	-	1st 0.300[(1)] + 1.1[(3)] 2nd 0.360[(1)] + 1.32[(3)] 3rd 0.480[(1)] + 1.76[(3)]	35	Authorisation intended for DE, FR, HU
Grapes (table and wine grapes)	SEU	F	*Plasmopara viticola*	WG	120 g/l[(1)] + 440 g/l[(3)]	Foliar spraying	BBCH 19 - 83	3	10 - 12	-	-	1st 0.300[(1)] + 1.1[(3)] 2nd	35	Authorisation intended for BG, ES, FR, GR, IT, PT, RO

Crop and/or situation	Member State or Country	F, G or I	Pests or group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
				type	conc of as	method kind	growth stage	number (range)	interval (days)	as (kg/hl)	water (l/ha)	as (kg/ha)		
												0.360[1] + 1.32[3] 3rd 0.480[1] + 1.76[3]		
Pepper	NEU + SEU	G	*Phytophthora capsici*	SC	300 g/l[1] + 225 g/l[2]	Foliar spraying	BBCH 10 - 89	3	7 - 10	-	-	0.24[1] + 0.18[2]	1	Authorisation intended for ES, IT, PT and NEU (MS not specified)
Cucurbits edible peel (cucumber / zucchini)	NEU	F	*Pseudoperonospora cubensis*	SC	300 g/l[1] + 225 g/l[2]	Foliar spraying	BBCH 11 - 89	1 - 3	7 - 10	-	-	0.24[1] + 0.18[2]	1	Not specified for which MS authorisation is intended
Cucurbits edible peel (cucumber / zucchini)	SEU	F	*Pseudoperonospora cubensis*	SC	300 g/l[1] + 225 g/l[2]	Foliar spraying	BBCH 11 - 89	1 - 3	7 - 10	-	-	0.24[1] + 0.18[2]	1	Authorisation intended for ES, IT
Cucurbits edible peel (cucumber / zucchini)	NEU +SEU	G	*Pseudoperonospora cubensis*	SC	300 g/l[1] + 225 g/l[2]	Foliar spraying	BBCH 11 - 89	1 - 3	7 - 10	-	-	0.24[1] + 0.18[2]	1	Authorisation intended for ES, IT, and NEU (MS not specified)
Cucurbits inedible peel (melon, water melon and pumpkin)	NEU	F	*Pseudoperonospora cubensis*	SC	300 g/l[1] + 225 g/l[2]	Foliar spraying	BBCH 11 - 89	1 - 3	7 - 10	-	-	0.24[1] + 0.18[2]	1	Not specified for which MS authorisation is intended
Cucurbits inedible peel (melon, water melon and pumpkin)	SEU	F	*Pseudoperonospora cubensis*	SC	300 g/l[1] + 225 g/l[2]	Foliar spraying	BBCH 11 - 89	1 - 3	7 - 10	-	-	0.24[1] + 0.18[2]	1	Authorisation intended for ES, IT
Lettuce (head lettuce and lamb lettuce)	NEU	F	*Bremia lactucae*	SC	300 g/l[1] + 225 g/l[2]	Foliar spraying	BBCH 10 - 49	1 - 3	7 - 10	-		0.24[1] + 0.18[2]	7	Not specified for which MS authorisation is intended
Lettuce (head lettuce and lamb lettuce)	SEU	F	*Bremia lactucae*	SC	300 g/l[1] + 225 g/l[2]	Foliar spraying	BBCH 10 - 49	1 - 3	7 - 10	-		0.24[1] + 0.18[2]	7	Authorisation intended for ES, IT, PT
Lettuce (head lettuce and lamb lettuce)	NEU + SEU	G	*Bremia lactucae*	SC	300 g/l[1] + 225 g/l[2]	Foliar spraying	BBCH 10 - 49	1 - 3	7 - 10	-		0.24[1] + 0.18[2]	7	Authorisation intended for ES, IT, PT, and NE (MS not specified)

(1) BAS 650 F
(2) Dimethomorph
(3) Metiram
- not indicated by applicant

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

BAS 650 F			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**10**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**DAR**	Source of ARfD:	**DAR**
Year of evaluation:	**2009**	Year of evaluation:	**2009**

The ADI as proposed by the RMS in the DAR is used for the provisional dietary risk assessment.

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
0,05	WHO Cluster diet B	0,02	Wine grapes	0,01	Lettuce	0,01	Tomatoes	
0,05	FR all population	0,04	Wine grapes	0,00	Lettuce	0,00	Lamb's lettuce	
0,03	PT General population	0,02	Wine grapes	0,00	Table grapes	0,00	Tomatoes	
0,03	ES adult	0,02	Lettuce	0,00	Wine grapes	0,00	Tomatoes	
0,02	WHO regional European diet	0,02	Lettuce	0,00	Tomatoes	0,00	Wine grapes	
0,02	WHO cluster diet E	0,02	Wine grapes	0,00	Lettuce	0,00	Table grapes	
0,02	WHO Cluster diet F	0,01	Lettuce	0,01	Wine grapes	0,00	Tomatoes	
0,02	IE adult	0,01	Wine grapes	0,00	Lettuce	0,00	Table grapes	
0,02	IT adult	0,02	Lettuce	0,00	Tomatoes	0,00	Table grapes	
0,02	ES child	0,02	Lettuce	0,00	Tomatoes	0,00	Peppers	
0,02	DE child	0,01	Table grapes	0,00	Tomatoes	0,00	Lettuce	
0,02	IT kids/toddler	0,01	Lettuce	0,00	Tomatoes	0,00	Table grapes	
0,02	UK Adult	0,01	Wine grapes	0,00	Lettuce	0,00	Tomatoes	
0,02	UK vegetarian	0,01	Wine grapes	0,01	Lettuce	0,00	Tomatoes	
0,02	DK adult	0,01	Wine grapes	0,00	Tomatoes	0,00	Table grapes	
0,02	NL general	0,01	Wine grapes	0,00	Lettuce	0,00	Table grapes	
0,01	NL child	0,01	Table grapes	0,00	Lettuce	0,00	Tomatoes	
0,01	DK child	0,01	Lettuce	0,00	Table grapes	0,00	Tomatoes	
0,01	WHO cluster diet D	0,00	Wine grapes	0,00	Tomatoes	0,00	Table grapes	
0,01	FI adult	0,00	Lettuce	0,00	Wine grapes	0,00	Tomatoes	
0,01	PL general population	0,00	Table grapes	0,00	Tomatoes	0,00	Lettuce	
0,01	UK Toddler	0,00	Table grapes	0,00	Tomatoes	0,00	Lettuce	
0,00	LT adult	0,00	Lettuce	0,00	Tomatoes	0,00	Potatoes	
0,00	FR toddler	0,00	Tomatoes	0,00	Table grapes	0,00	Potatoes	
0,00	SE general population 90th percentile	0,00	Tomatoes	0,00	Peppers	0,00	Potatoes	
0,00	FR infant	0,00	Table grapes	0,00	Courgettes	0,00	Potatoes	
0,00	UK Infant	0,00	Tomatoes	0,00	Potatoes	0,00	Table grapes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of BAS 650 F is unlikely to present a public health concern.

APPENDIX C – EXISTING EC MRLS

Currently no specific MRLs are established in Regulation (EC) No 396/2005. Default MRL of 0.01 mg/kg according to Art. 18(1)(b) is applicable.

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
Bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CS	capsule suspension
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DP	dustable powder
DT_{90}	period required for 90 percent dissipation (define method of estimation)
DTU	Danish Technical University
dw	dry weight
EC	European Community
EC	emulsifiable concentrate
ECD	electron capture detection
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionization detection
GAP	good agricultural practice
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre

HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10^{-6})
PRIMo	Pesticide Residues Intake Model
RMS	rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WG	water dispersible granule
WHO	World Health Organisation
WP	wettable powder